



PATENT COOPERATION TREATY

PCT**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference M/GUN-024-PC	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/003690	International filing date (<i>day/month/year</i>) 09 April 2003 (09.04.2003)	Priority date (<i>day/month/year</i>) 11 April 2002 (11.04.2002)
International Patent Classification (IPC) or national classification and IPC A61N 1/32		
Applicant	GUNDOLF, Ferdinand	

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 10 November 2003 (10.11.2003)	Date of completion of this report 22 July 2004 (22.07.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/003690

I. Basis of the report

1. With regard to the elements of the international application:*

the international application as originally filed
 the description:

pages _____ 1-14 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19)
 pages _____, filed with the demand
 pages _____ 1-8 _____, filed with the letter of 09 July 2004 (09.07.2004)

the drawings:
 pages _____ 1/3-3/3 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
 These elements were available or furnished to this Authority in the following language _____ which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
 the language of publication of the international application (under Rule 48.3(b)).
 the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

contained in the international application in written form.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority in written form.
 furnished subsequently to this Authority in computer readable form.
 The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

the description, pages _____
 the claims, Nos. 9-11 _____
 the drawings, sheets/fig _____

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

The amendments submitted with the letter of 9 July 2004 introduce substantive matter which, contrary to PCT Article 34(2)(b), goes beyond the scope of the international application as filed. The amendments are as follows:

In claim 1, the feature that "the piezoelectric element (33;34) is arranged...within the implant" has been introduced as an alternative to the arrangement within an implant pocket that opens toward the bone (cf. original claim 4). The application as originally filed contains no basis for such a broad definition. Rather, the application as originally filed discloses the following special embodiments: arrangement of the piezoelectric element in a longitudinal cavity of a threaded section of a bone screw (figures 1, 2, 8 and 9) or of a pin for the neck of a femur (figure 3), in openings in the bottom of a hip socket (figure 4), or in a stabilization element (figure 10) designed as an oblong half-tube. Therefore, it does not seem justifiable to generalize the definition to read "within the implant"; instead, the special arrangements should have been defined, insofar as they are not regarded as coming under the definition "within an implant pocket that opens toward the bone".

In establishing this examination report, the inclusion of the feature that "the piezoelectric element (33;34) is arranged...within the implant" was not taken into consideration, which means that in claim 1 (see lines 17-20) only the feature "within an implant pocket that opens toward the bone" was taken into consideration.

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International application No.

PCT/EP 03/03690

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	<u>1-8 (subject to proviso)</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-8 (subject to proviso)</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-8</u>	YES
	Claims		NO

2. Citations and explanations

This report makes reference to the following document:

D1: EP 1 023 872 A (mentioned in the application).

1. Subject to the proviso indicated in Box I, the subject matter of independent claim 1 meets the PCT requirements for novelty (PCT Article 33(2)) and inventive step (PCT Article 33(3)), for the following reasons:

D1, which is regarded as the prior art closest to the subject matter of claim 1, discloses a device for promoting bone growth (figure 2A, cf. column 6, lines 29-35) that comprises an implant (60) and a piezoelectric element (65a, 65b), the implant forming one pole (column 6, lines 24-28 and 36-38) and the piezoelectric element being arrangeable within an implant pocket that opens toward the bone (column 6, lines 12-17, column 7, lines 10-13 and column 8, lines 16-22).

The subject matter of claim 1, insofar as it refers to a device comprising a piezoelectric element arranged within an implant pocket that opens toward the bone (see Box I), differs from the known device

in that a contact element made of electrically conductive material compatible with the human body is additionally provided, the contact element being arranged such that it comes into contact only with bones and the piezoelectric element and forming the second pole of the piezoelectric element.

The problem to be solved by the present invention can be regarded as that of improving the field distribution. In the embodiments described in D1 in which the implant and a contact element (spatially separated electrodes) are provided as poles, the piezoelectric element is arranged spatially separately from the implant (cf. figure 1). However, when a piezoelectric element is attached to the implant, no contact element is provided (figure 2A). Therefore, D1 does not render obvious the combination of features proposed in claim 1 of the present application.

2. Claims 2-8 are dependent on claim 1 and therefore likewise meet (subject to the reservation explained in Box I) the PCT requirements for novelty and inventive step.